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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,432	07/07/2003	Roger D. Tung	VPI/98-101 CIP CON DIV US	2579

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EXAMINER	
O SULLIVAN, PETER G	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
02/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,432	TUNG ET AL.	
	Examiner	Art Unit	
	Peter G. O'Sullivan	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-9,11 and 13-39* is/are pending in the application.

4a) Of the above claim(s) *35-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6-9, 11, 13-34 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03 July 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-3, 6-9, 11, 13-34 and 39 are pending in this application which should be reviewed for errors. An example of error occurs in claim 23 of applicants' amendment wherein the claim is not on a separate line below claim 23. In response to the restriction requirement, applicants elected group I, claims 1-34, without traverse. Accordingly, claims 35-38 and applicants' non-heterocyclic containing compounds are held withdrawn from consideration. Upon the further requirement for the election of a single disclosed species, applicants elected the species of compound 108 on page 22 of the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-9, 11, and 13-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention in the instant case, has claims which embrace a wide range of chemically and physically distinct compounds, wherein T, K, V, M, A2, R18, R19, n, L and W are a variety of functionally divergent groups, including aliphatic, heteroaliphatic, aryl and heteroaryl rings. The scope of applicants' compound claims reads on a plethora of aliphatic, heteroaliphatic, aryl and heteroaryl substituents and linking moieties. A2 and R18 together may be, for example, sulfonyl or hydrazinylcarbonyl. K and V together may be, for example, a bond or

sulfonylhydrazine. The nature of these substituents is is vague in that it is not clear how large the substituent may be, the position of the heteroatoms and point of attachment of the heterocyclic moieties, etc. While several specific compounds are disclosed, there is insufficient guidance for preparing additional serine protease inhibitors which would be effective in the treatment or prevention of hepatitis C as well as any other disease which may be associated with serine proteases.

Testing is provided for only a few of the claimed compounds at pages 76-79 of the specification. Examples should be of sufficient scope as to justify the scope of the claims. However the generic claims are much broader in scope than is represented by testing. Note the broad definitions for T, K, V, M, A2, R18, R19, n, L and W in the generic claims. These definitions embrace many structurally divergent groups not represented in the testing. Markush claims must be provided with support in the disclosure. Markush claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See In re Fouche 169 USPQ 429. The compounds tested are not seen as adequately representative of the compounds encompassed by the extensive Markush groups instantly claimed for the uses instantly asserted and claimed.

This area of activity can be expected to be highly structure specific and unpredictable as is generally true for chemically based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably

extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested.

In view o the breadth of the claims, the unpredictability in this area of activity, and the limited amount of guidance and examples in the specification, one skilled in the art would have to undergo an undue amount of experimentation to make and/or use the claimed compounds.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-9, 11, and 13-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendments to the claims lists the claims with boxes showing deleted subject matter that covers part of the claims themselves.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-9, 11, 13-34 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,608,067. Although the conflicting claims are not identical, they are not patentably distinct from each other because they generically overlap.

No claim is allowed.

Any inquiry concerning this communication should be directed to Peter G. O'Sullivan at telephone number (571)272-0642.

/Peter G O'Sullivan/

Primary Examiner, Art Unit 1621